

# Why Is Health Care Regulation So Complex?

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The array of regulations that govern health care can seem overwhelming to people who work in the industry. Almost every aspect of the field is overseen by one regulatory body or another, and sometimes by several. Health care professionals may feel that they spend more time complying with rules that direct their work than actually doing the work itself.

The scope and complexity of health care regulation is the subject of a book that I recently published, entitled *Health Care Regulation in America: Complexity, Confrontation and Compromise*.<sup>1</sup> With apologies for some admitted self-promotion, I'd like to summarize my conclusions, which may add a context for the topic.

My book describes an underlying logic behind the bewildering regulatory maze. The tangled web of health care regulation arises largely from a set of confrontations between opposing interests that created the system. Fortunately, an ongoing process of compromise keeps things in balance. To understand these forces is to appreciate why the complexity may actually serve a purpose.

## THE NATURE OF HEALTH CARE REGULATION

The pervasive nature of health care regulation stems from the fundamental concerns that are at stake. Most observers acknowledge that some form of oversight is needed when factors as essential as life and health are involved. Even those who are especially suspicious of heavy-handed government bureaucracy see a public interest in some form

of external supervision of this field. Policy debates, for the most part, swirl not around whether oversight should exist but, instead, around the way it should be structured.

However, the present regulatory structure is neither uniform nor consistent. A broad range of regulatory bodies and programs apply in different ways to various aspects of the industry. Health care regulations are developed and enforced by all levels of government—federal, state, and local—and also by a large assortment of private organizations. At times, they operate without coordination.

## THE ORIGINS AND EXTENT OF COMPLEXITY

The origins of this complex system lie in a series of turf wars between opposing interests that have been waged in one form or another over the past 150 years. The contest between federal and state authority is enshrined in the federalist structure of American government, and the debates of today echo early disputes over which kinds of power should reside at each level. Most of the power to govern day-to-day activities resides with the states under the Constitution, but it is subject to pre-emption at the federal level when various enumerated concerns come into play, such as defense, foreign relations, and interstate commerce.

This division of control created a source of ongoing tension in health care oversight from the start. To take a long-standing example, basic oversight of many of the central players in the health care system, including physicians, hospitals, and insurance companies, is accomplished by agencies at the state level. In every case, however, it is coordinated by federal authorities. Similarly, most public health programs, including sanitation, restaurant inspections, and investigations of epidemics, are the responsibility of state and local regulators, but the federal Centers for Disease Control

and Prevention (CDC) serves as an essential resource for collaboration on a national level.

Private regulators entered the scene in the early 20th century. The American Medical Association (AMA) sponsored the creation of a number of organizations that remain central today in the oversight of the medical profession, including those that accredit medical schools, administer licensure examinations, and certify specialists. These bodies supplement the work of governmental regulators. State medical boards, for example, use privately administered examinations in granting medical licenses, and the Medicare program relies on specialty certification as an indicator of physician quality. Along similar lines, the hospital industry accredits its own members as a supplemental step to state licensure through the Joint Commission (JCAHO).

## THE REGULATORY MAZE: TWO EXAMPLES

As a result of this network of oversight bodies, those individuals and organizations subject to regulation must turn to multiple competing authorities for guidance. Two examples illustrate this dynamic.

The path to practicing medicine is paved with an array of regulatory hurdles implemented by an assortment of bureaucracies. A potential physician must attend a medical school that has received accreditation by a private body, take a national examination administered by another nongovernmental organization, obtain licensure from a state medical board, complete a hospital residency that is funded and governed by the federal Medicare program, achieve certification from a private specialty board, and obtain clinical privileges at a hospital that may operate as either a private or public entity. To receive payment for services and actually earn a living, it is often also necessary for a physician to qualify for



participation in Medicare and in the network of a managed care organization (MCO).

The path to marketing a new drug is similarly cumbersome. A pharmaceutical company must start by protecting its invention with a patent that is issued by the federal Patent and Trademark Office (PTO). It must then receive permission to conduct clinical testing from the federal Food and Drug Administration (FDA), which for many products culminates in review of the results by an advisory committee composed of private scientists. After approval for marketing is received in the form of a New Drug Approval (NDA), the manufacturer must adhere to marketing restrictions contained in the NDA.

Next, in order to sell the drug widely, the manufacturer must obtain a place for it on the formularies of private pharmacy benefit management companies (PBMs), which administer reimbursement plans. Ideally, the drug will also be included in the standards of care promulgated by private medical specialty societies.

After all of these steps, the drug still cannot be sold unless it is prescribed by physicians and is dispensed by pharmacists who are subject to licensure and a range of other regulatory requirements.

## THE LOGIC BEHIND REGULATORY COMPLEXITY

Is this complexity of health care regulation merely a result of a series of historical accidents and bureaucratic turf wars, or does it serve a purpose? The system's intricacy may make it inefficient, but it actually fits quite well with the American temperament. It is driven by an interplay of competing forces that seek to have their interests represented.

Different levels of government vie with one another for supremacy, as they have since the founding of the republic. This system of checks and balances makes it less likely that any one level, federal or state, will become too powerful, and it ensures that the overall system will receive input from each. The regulatory structure also reflects a form of public-private partnership. Private organizations, such as the Joint Commission and medical specialty boards, which are composed of professionals who actually work in the field, inject technical expertise.

These organizations are balanced by government agencies, which provide a more disinterested external perspective that is presumably less subject to economic self-interest.

In essence, the system benefits by receiving regulatory input from varying perspectives. State and local agencies are often closest to the actual provision of health care and the most sensitive to regional needs. Federal oversight is usually necessary to provide national coordination, for example, to prevent physicians who have been disciplined by a medical board from gaining licensure in another state. Private organizations offer the deepest expertise in the clinical aspects of care.

Rather than hindering its progress, the complex system of regulation, for all of its flaws, may actually have served to support and nurture the overall enterprise.

## SYSTEM SHORTCOMINGS

This explanation is not meant to suggest that the system is without its share of shortcomings, because some of them are substantial. Critics charge that private regulatory bodies are often more interested in safeguarding the reputation and economic status of their industries and professions than in protecting the public. State regulators, particularly those in smaller jurisdictions, may be subject to excessive influence by those they are supposed to oversee. Federal agencies may be slow, bureaucratic, and inefficient.

Moreover, in some areas of regulation, the division of authority is not clearly outlined, a drawback that has led at times to chaotic results. A prime example is the oversight of health insurance. States take the lead in regulating insurance, but the federal government pre-empts some state authority over employer-sponsored health coverage under the Employee Retirement Income Security Act of 1974 (ERISA). The lines of responsibility are not clearly defined in the law, and they have been sub-

ject to a series of equally confusing court decisions.

## CONSEQUENCES OF THE REGULATORY SYSTEM

Despite the complicated and inefficient nature of its oversight, American health care has flourished over the past hundred years. Rather than hindering its progress, the complex system of regulation, for all of its flaws, may actually have served to support and nurture the overall enterprise.

Consider, for example, the public confidence that is engendered in the competence of physicians through licensure requirements and in the safety and efficacy of prescription drugs through the FDA approval process. These programs enhanced overall respect for major elements of the health care system and greatly expanded markets for the goods and services that they provide. Regulatory programs that include major funding components, such as Medicare and research support administered by the National Institutes of Health (NIH), serve an additional role of creating a financial base for key sectors of the industry.

Viewing the system in this way may help to provide perspective for those who have to navigate it. It is also important to consider the underlying nature of the system, with both its positive and negative elements, in evaluating proposals for reform.

A more thorough presentation of the regulatory structure of the health care industry and the themes that drive it can be found in my book.

## REFERENCE

1. Field RI. *Health Care Regulation in America: Complexity, Confrontation and Compromise*. New York: Oxford University Press, 2007. ■